



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Paper No.

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON MA 02110

MAILED

NOV 27 2009

OFFICE OF PETITIONS

In re Patent No. 7,544,657 :
Ebbehøj et al. : DECISION ON
Application No. 10/529,858 : REQUEST FOR
Issue Date: June 9, 2009 : RECONSIDERATION OF
Filed: April 26, 2006 : PATENT TERM ADJUSTMENT
Attorney Docket No. : UNDER 37 CFR 1.705
50412/022002 :

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT, filed on August 10, 2009. Patentees request that the determination of patent term adjustment be corrected from 34 days to 509 days.

The request for reconsideration of patent term adjustment is **GRANTED TO THE EXTENT INDICATED.**

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of two hundred ninety-nine (299) days.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to this decision. No extensions of time will be granted under § 1.136.

BACKGROUND

On June 9, 2009, the application matured into U.S. Patent No. 7,544,657, with a revised patent term adjustment of 34 days. No additional days of patent term adjustment were entered at

issuance under the three-year pendency provision. Given the applicant delay of 134 days, the patent issued with a revised patent term adjustment of 34 (168 - 134) days.

On August 10, 2009, patentees timely submitted this request for reconsideration of patent term adjustment (with required fee), asserting that the correct number of days of Patent Term Adjustment is 509 days based, in part, on the courts' interpretation of the overlap provision as set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentee asserts that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintains that the total non-overlapping PTO delay under §154(b)(1)(A) & (B) is 601 (168 + 433) days as these periods do not occur on the same day. Further, patentees assert that the 42 day period of Office delay under 37 CFR 1.704(c)(10) for the filing of drawings after the mailing of the notice of allowance should be removed. Accordingly, patentees assert that the applicant delay should be 92 days (134 - 42), and entitlement to 509 (601 - 92) days of patent term adjustment.

OPINION

A review of the record indicates that the Office did not use the correct 35 U.S.C. 371(b) national stage commencement date of April 2, 2005, in calculating the period of adjustment under 37 CFR 1.703(b). As stated in 37 CFR 1.703(b), the period of adjustment under § 1.702(b) is the number of days in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) in an international application and ending on the date a patent was issued. While the date of completion of all 35 U.S.C. 371 requirements, April 26, 2006, is the date used in calculation of the examination delay under 37 CFR 1.702(a)(1), the date the national stage commenced under 35 U.S.C. 371(b), April 2, 2005, is used to determine the Three Year Delay under 37 CFR 1.703(b).

Pursuant to 37 CFR 1.703(b), the period of adjustment under 37 CFR 1.702(b) should be 433 days, counting the number of days beginning on April 3, 2008, the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b), and ending on the date the patent issued, June 9, 2009.

Nonetheless, patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark*

Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f)* and of the *United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C.

154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the date of commencement, April 2, 2005, and ending on the date of the issuance of the application as a patent, June 9, 2009 (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1), 168 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the issuance of the patent. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), 433 days of patent term adjustment accrued for Office issuance of the patent more than 3 years after the commencement date.

The 433 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 168 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 433 days and the 168 days is neither permitted nor warranted. 433 days is the actual number of days issuance of the patent was delayed.

Accordingly, at issuance, 265 (433 - 168) additional days (not 433 days) should have been entered.

Patentees' contention that the 42 day period of reduction for the filing of replacement drawings after the mailing of a notice of allowance should be removed is not persuasive. Patentees assert that there should not be a reduction in patent term adjustment because the replacement drawings were requested by the Office in the Notice to File Corrected Application Papers *Notice of Allowance Mailed* mailed on April 9, 2009, which stated that replacement drawings were required because Sheet 7 of the drawings did not contain a figure label.

In this regard, MPEP 2701 states, in pertinent part:

37 CFR 1.704(c)(10) establishes submission of an amendment under 37 CFR 1.312 or other paper after a notice of allowance has been given or mailed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The submission of amendments (or other papers) after an application is allowed may cause substantial interference with the patent issue process. Certain papers filed after allowance are not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application. See Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been Mailed, 1247 Off. Gaz. Pat. Office 111 (June 26, 2001). The submission of the following papers after a "Notice of Allowance" is not considered a failure to engage in reasonable efforts to conclude processing or examination of an application: (1) Fee(s) Transmittal (PTOL-85B); (2) Power of Attorney; (3) Power to Inspect; (4) Change of Address; (5) Change of Status (small/not small entity status); (6) a response to the examiner's reasons for allowance or a request to correct an error or omission in the "Notice of Allowance" or "Notice of Allowability;" and (7) letters related to government interests (e.g., those between NASA and the Office). Papers that will be considered a failure to engage in reasonable efforts to conclude processing or examination of an

application include: (1) a request for a refund; (2) a status letter; (3) amendments under 37 CFR 1.312; (4) late priority claims; (5) a certified copy of a priority document; (6) drawings; (7) letters related to biologic deposits; and (8) oaths or declarations. 37 CFR 1.704(c)(10) provides that in such a case the period of adjustment set forth in 37 CFR 1.703 shall be reduced by the lesser of: (1) the number of days, if any, beginning on the date the amendment under 37 CFR 1.312 was filed and ending on the mailing date of the Office action or notice in response to the amendment under 37 CFR 1.312 or such other paper; or (2) four months.

Drawings are not among the types of papers which will not be considered a failure to engage in reasonable efforts to conclude processing or examination. Rather, the O.G. and the MPEP state that drawings are among the types of papers which are considered a failure to engage in reasonable efforts to conclude processing or examination. Moreover, 37 CFR 1.704(c)(10) does not distinguish between papers which were expressly requested by the Office and those which were not expressly requested. Patentees filed the drawings after the mailing of the notice of allowance on April 29, 2009. On June 9, 2009, 42 days after drawings were filed, the patent issued. Accordingly, a 42 day period of reduction is warranted and will not be removed.

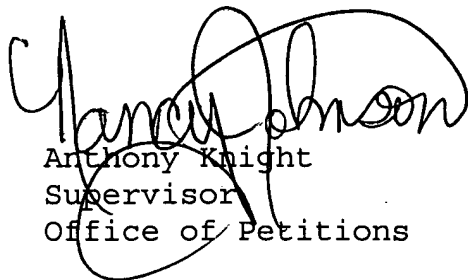
CONCLUSION

Considering the applicant delay of 134 days, the patent term adjustment at issuance is 299 (168 + 265 - 134) days.

The application file is being forwarded to the Certificates of Correction Branch of issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by two hundred ninety-nine (299) days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Senior Petitions Attorney Douglas I. Wood, at (571) 272-3231.

A handwritten signature in black ink, appearing to read "Anthony Knight", is written over the typed name and title. The signature is stylized with a large, looping initial 'A' and a long horizontal stroke extending to the right.

Anthony Knight
Supervisor
Office of Petitions

Encl: DRAFT Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 7,544,657 B2

DATED : Jun. 9, 2009

INVENTOR(S) : Ebbehøj et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (34) days

Delete the phrase “by 34 days” and insert – by 299 days--